Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Early nasal intermittent positive pressure ventilation versus continuous positive airway pressure in preterm infants with respiratory distress syndrome

Protocol summary

Summary

The aim of this study was to compare the prognosis and side effects in premature neonates with gestational age between 28 to 34 weeks at Fatemiyeh Hospital affiliated to Hamedan University of Medical Science with respiratory distress syndrome that are treated with nasal intermittent positive pressure ventilation or nasal continuous positive airway pressure. This clinical trial was performed on sixty premature neonates with birth weight between 1000 to 2000 grams with respiratory distress within 6 hours of birth and 2 or more of symptoms of respiratory distress or Silverman-Anderson score of 6 or 7 were eligible and patients are classified into 2 groups. The subjects were randomly assigned in two groups to receive early nasal continous positive airway pressure and early nasal intermittent positive pressure ventilation. All newborns were observed for seven days about the need for mechanical ventilation, adverse outcomes and death. In these time pneumothorax, patent ducts steroids (PDA), lung hemorrhage, disseminated intravascular coagulopathy (DIC), icterus, sepsis was determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072618598N1**
Registration date: **2015-09-25, 1394/07/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-25, 1394/07/03

Registrant information

Name

Mohamad Kazem Sabzehei

Name of organization / entity

Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Early nasal intermittent positive pressure ventilation versus continuous positive airway pressure in preterm infants with respiratory distress syndrome

Public title

Comparison of non-invasive treatment through the nose for the treatment of respiratory immaturity in preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

All consecutively born preterm infants with gestational

age between 28 to 34 weeks, admitted to Fatemiyeh neonatal intensive care unit with respiratory distress syndrome Inclusion criteria: approved RDS; gestational age between 28 to 34 weeks; neonates with 72 hours age after delivery. Exclusioncriteria: the neonates aith APGAR score less than 3 at five minute after birth; those whom mother had rupture of the membrane for more than three weeks; severe malformation; chromosomal anomalies such as trisomy of 13,18 and 21; pneumonia; pneumothorax

Age
From **1 day** old to **1 day** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamedan University of Medical Sciences

Street address
Hamedan university of medical science, Daneshgah street, Pajohesh square

City
Hamedan

Postal code

Approval date
2014-11-25, 1393/09/04

Ethics committee reference number
4201/9/35/16/پ

Health conditions studied

1

Description of health condition studied
treatment

ICD-10 code
p22, p22.0

ICD-10 code description
Respiratory distress of newborn

Primary outcomes

1

Description
survival rates in 7days

Timepoint
during hospitalization and using NIPPV and NCPAP

Method of measurement
comparing survival rates

Secondary outcomes

1

Description
need to mechanical ventilation

Timepoint
during hospitalization and using NIPPV and NCPAP

Method of measurement
during hospitalization and using NIPPV and NCPAP

2

Description
lung hemorhage

Timepoint
during hospitalization and using NIPPV and NCPAP

Method of measurement
during hospitalization and using NIPPV and NCPAP

3

Description
pnemothorax

Timepoint
during hospitalization and using NIPPV and NCPAP

Method of measurement
during hospitalization and using NIPPV and NCPAP

4

Description
NEC

Timepoint
during hospitalization and using NIPPV and NCPAP

Method of measurement
during hospitalization and using NIPPV and NCPAP

5

Description
sepsis

Timepoint
during hospitalization and using NIPPV and NCPAP

Method of measurement
during hospitalization and using NIPPV and NCPAP

6

Description
mortality
Timepoint
during hospitalization and using NIPPV and NCPAP
Method of measurement
during hospitalization and using NIPPV and NCPAP

Intervention groups

1

Description
Using of early nasal continous positive airway pressure at least 48 hours with the maximum positive end expiratory pressure: 5 cmH2o and Fio2: 60%
Category
Treatment - Other

2

Description
Using of early nasal intermittent positive pressure ventilating at least 48hours with the maximum PEEP: 5 cmH2o, Fio2: 60%, PIP: 16 cmH2o, Resirstory rate: 30/min
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemiyeh Hospital
Full name of responsible person
Maryam Nasresfahani
Street address
Hamedan University of Medical Sciences, Daneshgah street, Pajohesh square
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Scinences
Full name of responsible person
Dr Mohamad Yosef Alikhani
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Daneshgah street, Pajohesh square, Hamedan
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Scinences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Mohamad Kazem Sabzehei
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty